PART VII
RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

RHB 7.1 Scope. This part establishes special requirements for analytical X-ray equipment. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of these regulations.

RHB 7.2 Electron Microscopes. Electron microscopes shall be exempt from the other requirements of this Partexcept that they:

7.2.1 Shall be registered with the Department, and

7.2.2 Shall be installed, shielded, and operated in such a manner that no one shall be exposed beyond the limits defined in Section 3.4.1 of these regulations.

RHB 7.3 General Requirements for All Analytical X-ray Equipment.

7.3.1 Registration. All requirements of RHB 2.3 and 2.4 apply.

7.3.2 Posting. Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION- X-RAY EQUIPMENT", or words having similar intent.

7.3.3 Labeling. All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol, and

7.3.3.1 A label bearing the words "Caution - Radiation - This Equipment Produces Radiation When Energized" or words having a similar intent shall be placed near any switch which energizes an x-ray tube.

7.3.3.2 A sign bearing the words "Caution- High Intensity X-ray Beam", or words having a similar intent on the x-ray source housing, shall be placed in the area immediately adjacent to each tube head. The sign shall be so located that it is clearly visible to any person operating, aligning, or adjusting the unit, or handling or changing a sample.

7.3.4 Warning Lights.

7.3.4.1 An easily visible warning light labeled with the words "X-RAY ON," or words having a similar intent, shall be located near any switch that energizes an X-ray tube and shall be illuminated only when the tube is energized.

7.3.4.2 Warning lights shall have fail-safe characteristics.

7.3.5 Safety Devices.

7.3.5.1 Any temporary alteration to safety devices, such as by-passing interlocks or removing shielding shall be:

7.3.5.1.1 Approved in advance by the radiation safety officer.

7.3.5.1.2 Specified in writing and posted near the x-ray tube housing so that other individuals will know the existing status of the x-ray apparatus.

7.3.5.1.3 Terminated as soon as possible.

7.3.5.1.4 Recorded and the record maintained for inspection by the Department. This record should contain such information as date alteration was made, type of alteration, length of time unit remained in the altered condition, and signed by the individual who made the alteration and the individual who restored the unit to original condition.

7.3.5.2 Tests of safety devices such as interlocks, shutters, and warning lights shall be conducted at intervals not to exceed 3 months for all operable analytical x-ray equipment. Records of such tests shall be maintained for inspection by the Department.

7.3.5.3 The inspection and testing of safety devices shall not be a substitute for a radiation protection survey.

7.3.5.4 Interlocks shall not be used to de-activate the x-ray tube, except in an emergency or during testing of the interlock system. After such shut-off, it shall be possible to restore the machine to full operation only from the control panel.

7.3.5.5 Unused ports on radiation source housings shall be secured in the closed position in a manner to prevent inadvertent opening.

7.3.6 Each x-ray tube housing shall be so constructed that with all shutters closed the leakage radiation measured at a distance of 5 cm from its surface does not exceed 2.5 milliRoentgen in any given hour at any specified tube rating.

7.3.7 Generator Cabinet. Each X-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance from its surface to 0.25 milliRoentgen in any given hour.

7.3.8 Repair or Modification of X-ray Tube System. Except as specified in 7.3.5.1, no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

RHB 7.4 Additional Requirements for Open Beam Configuration X-ray Equipment.

7.4.1 Safety Device. A device which prevents the entry of any portion of an individual's body into the primary beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configuration x-ray equipment. A registrant may apply to the Department for an exemption from the requirement of a safety device. Such application shall include:

7.4.1.1 A description of the various safety devices that have been evaluated.

7.4.1.2 The reason each of these devices cannot be used, and

7.4.1.3 A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of the safety devices.

7.4.2 The operator shall be in immediate attendance at all times when the equipment is in operation except when the area is locked to protect against unauthorized or accidental entry.

7.4.3 When not in use, equipment shall be secured in such a manner as to be inoperable by unauthorized persons.

7.4.4 Warning Devices. Open-beam configuration x-ray equipment shall be provided with a readily discernible indication of:

7.4.4.1 X-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner, or

7.4.4.1 Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

7.4.5 Warning devices shall be labeled so that their purpose is easily identified.

7.4.6 Warning devices shall have fail-safe characteristics.

7.4.6.1 Where couplings exist, e.g., between the x-ray tube and the collimator of the diffractometer, etc., they shall prevent radiation from escaping the coupling.

7.4.6.2 Each port of the radiation source housing shall be provided with a beam shutter interlocked with the x-ray apparatus coupling, or collimator, in such a way that the port will be open only when the collimator or coupling is in place.

RHB 7.5 Additional Requirements for Enclosed Beam X-ray Equipment.

7.5.1 The radiation source, sample, detector and analyzing crystal (if used) shall be enclosed in a chamber or coupled chambers that cannot be entered by any part of the body during normal operation.

7.5.2 The sample chamber closure shall be interlocked with the x-ray tube high voltage supply or a shutter in the primary beam so that no x-ray beam can enter the sample chamber while it is open unless the interlock has been conspicuously and deliberately defeated. The interlock required by this section shall be of fail-safe design or adequate administrative controls shall be exercised to ensure operations will not continue without a proper functioning interlock.

RHB 7.6 Area Requirements for All Analytical X-ray Equipment.

7.6.1 Radiation levels. The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or have access control such that no radiation in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in RHB 3.2.2. These levels shall be met at any specified tube rating.

7.6.2 Surveys, Tests and Inspections. Radiation surveys, as required by 1.4.1 of all analytical x-ray systems to show compliance with7.6.1 shall be performed and records kept and available for review:

7.6.2.1 Upon installation of the equipment and at least once every twelve (12) months thereafter.

7.6.2.2 Following any change in the initial arrangement, number, or type of local components in the system.

7.6.2.3 Following any change in operating parameters.

7.6.2.4 Following any maintenance requiring the disassembly or removal of a local component of the system.

7.6.2.5 During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed.

7.6.2.6 Any time a visual inspection of the local components in the system reveals an abnormal condition.

7.6.2.7 Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the Radiation Protection Guides (radiation dose limits).

7.6.3 Radiation survey measurements shall not be required if a registrant can demonstrate compliance to the satisfaction of the Department with 7.6.1 in some other manner.

7.6.4 Tests and inspections of all safety devices shall be performed at least yearly to insure their proper operation. The results shall be documented and available for review.

7.6.5 Radiation in excess of the limits specified in RHB 7.3.6 and RHB 7.3.7 shall be eliminated prior to using the analytical x-ray equipment.

RHB 7.7 Radiation Survey Instruments.

7.7.1 The radiation survey instrument used to meet the requirements of RHB 8.13 shall have a minimum operation range not to exceed 5 milliRoentgens (2.58×10^{-4} C/kg) per hour.

7.7.2 Each radiation survey instrument shall be calibrated:

7.7.2.1 At intervals not to exceed 12 months and after each instrument servicing;

7.7.2.2 Such that accuracy within 20 percent traceable to a national standard can be demonstrated; and

7.7.2.3 At two or more widely separated points, other than zero, on each scale, and

7.7.2.4 At energy levels encountered.

7.7.3 Records of these calibrations shall be maintained for inspection by this Department.

RHB 7.8 Personnel Requirements.

7.8.1 Instruction. No person shall be permitted to operate, repair, modify, or maintain analytical x-ray equipment unless such person has received instruction and demonstrated competence in:

7.8.1.1 Identification of radiation hazards associated with the use of the equipment;

7.8.1.2 Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

7.8.1.3 Proper operating procedures for the equipment;
7.8.1.4 Radiation survey instruments: operation, calibration, limitations, and survey techniques;

7.8.1.5 Characteristics of x-radiation;

7.8.1.6 Units of radiation dose;

7.8.1.7 Personnel monitoring and the use of personnel monitoring equipment;

7.8.1.8 Symptoms of an acute localized exposure; and

7.8.1.9 Proper procedures for reporting an actual or suspected overexposure.

7.8.1.10 The regulations contained in this Part, Part IX, and the applicable sections of Part III.

7.8.2 Instruction and demonstration of competence shall be documented in writing and these records shall be available for review.

7.8.3 Procedures. Normal operating procedures shall be written and available to all analytical and research and development workers. No person shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such person has obtained written approval of the radiation safety officer.

7.8.4 A copy of instructions provided as required by RHB 7.8.1 and a copy of normal operating procedures as required by RHB 7.8.3 shall be provided to the Department upon request.

RHB 7.9 Personnel Monitoring.

7.9.1 Personnel monitoring shall be required as outlined in RHB 3.12.

7.9.2 Personnel monitoring devices shall be assigned to and only worn by one individual.

7.9.3 Finger or wrist dosimetric devices shall be provided to and shall be used by:

7.9.3.1 Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

7.9.3.2 Personnel maintaining analytical or research and development x-ray equipment if the maintenance procedures required the presence of a primary x-ray beam when any local component in the analytical or research and development x-ray system is disassembled or removed.

7.9.4 Reported dose values shall not be used for the purpose of determining compliance with Section 3.3 of these regulations unless evaluated by a qualified expert.